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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,728	SELVAN, GOWRI PYAPALI	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 25 March 2005 is acknowledged and has been entered.

Claim Objections

2. Claim 1 is objected to because of the following informalities: The phrase "converting the detected beam...capture zones; and" (lines 10-13) seems to be missing punctuations and includes an extra term. Because line 12 ends with the phrase "cells captured at the capture zone" and line 13 begins with "counting captured cells", it seems as if there should be a comma at the end of line 12. In addition, both lines 10 and 13 end with "; and". Should the first term be deleted? Appropriate correction is required.

3. Claim 7 is objected to because of the following informalities: The term "capture" (line 2) seems like it should be "capture zone". Appropriate correction is required.

4. Claim 32 is objected to because of the following informalities: The term "strepatavidin" (line 1) seems to be misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 18-20 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 18 recites the limitation "capture molecules" in line 3. There is insufficient antecedent basis for this limitation in the claim. The parent claims of 1 and 17-18 disclose a “cell capture agent”, but there is no recitation of the “capture molecules”.

8. Claim 32 is vague and confusing since it is unclear what the structural or functional relationships between the streptavidin layer, first antibody, and second antibody are. Are they layered on top of one another, are the first and second antibodies each on the streptavidin layer, or is another situation claimed?

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-15, 17-22, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238).

In the instant claims, Sheppard, Jr. et al reference teaches the steps of applying a sample to a detection or cell accumulation chamber of a platform (i.e. providing a sample of cells in a chamber in a disc), wherein the term "platform" is intended to encompass any solid support structure providing a surface or comprising a chamber that can be treated to comprise a specific binding reagent (i.e. chamber including at least one capture zone with a capture agent), wherein a binding chamber 24 is connected to a sample inlet port 21 (i.e. inlet port), and wherein the platform also includes air outlet ports (i.e. vent port). See column 8, lines 14-25; column 10, lines 15-18; column 13, line 56 to column 14, line 5; column 14, lines 6-7; and Figure 2. In addition, Sheppard, Jr. et al also teach that the detection system can comprise a component of a device manipulating the platform, preferably comprising an optical detecting means and that the disk can be loaded and spun (i.e. loading the disc into an optical reader; rotating the disc). See column 14, lines 61-63; column 26, lines 55-56.

In addition, Sheppard, Jr. et al also teach the steps of actuating means for positioning a light source on the surface of the platform and having photodetectors to optimally detect optical absorbance/transmittance or other optical signals (i.e. directing an incident beam of electromagnetic radiation to the capture zone; detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone), which are processed and translated into data including the number of cells on the platform (i.e. converting the detected beam into an output signal; analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone; counting captured cells), and wherein the device can also be provided having an interface with an integrated computer having image-processing features. See column 21, lines 57-67 and column 31, lines 31-39. Furthermore, Sheppard, Jr. et al reference teaches that the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or detection chamber are treated with said specific binding reagent and others are not in a recognizable manner such that each of a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber of the platform, thereby providing a pattern of distinct specific binding reagents on the platform, including alternating strips, checks, concentric circles, and a "bar code", and wherein there can be multiple detection chambers arrayed serially. See column 9, lines 5-7; column 10, lines 59-64; column 11, lines 1-25; and Figure 4E.

Although Sheppard, Jr. et al reference does not explicitly teach the limitations of rotating the disc "so as to separate different cell types into different capture zones" and

counting captured cells "in each of the capture zones", the instant reference teaches the limitations by disclosing disc rotation, cell counting, and a series of separate binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since Sheppard, Jr. et al reference teaches the rotation of the disc, centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Multiple cell types in a fluid sample would be captured by different specific binding reagents in different regions of the disc, either in separate detection chambers, or in different regions of the "bar code" or concentric circles within a detection chamber, thereby separating different cell types into different capture zones and allowing counting of the cells in each of the zones.

However, Sheppard, Jr. et al reference fails to teach that the output includes counts for CD4 and CD8 cells.

Sizto et al reference discloses determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD8 T-cell ratios, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and to determine the progression of AIDS. See column 6, lines 17-33.

It would have been obvious to modify the method of Sheppard, Jr. et al with determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD8 T-cell ratios, as taught by Sizto et al, in order to determine the presence of

cells within a particular subclass per unit volume in a sample, and to determe the progression of AIDS. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in detecting CD4 and CD8 cells, as taught by Sizto et al, in the method of Sheppard, Jr. et al, since Sheppard, Jr. et al teach the detection and quantification of cells, and determining the number of CD4 and CD8 cells is one example of detecting and quantifying cells.

In regards to claim 2, Sheppard, Jr. et al teach that the platform surface is internal to the disc and is enclosed (i.e. bounded on opposite sides) by a top layer (i.e. cap) and a bottom layer (i.e. substrate). See Figures 5A-E. In reference to the figures, the focus of the light from the light source 54 is on the surface of the chamber where the cells are located (see column 14, lines 39-58), and therefore the surface can be considered as part of the substrate, indicated above as the bottom layer. The top layer can be considered a cap since it is superior to the chamber space and opposite the substrate.

In regards to claim 3, Sheppard, Jr. et al teach that platforms can comprise a reflective surface (i.e. reflective layer) and the detector and the light source are positioned on the same side of the platform. See column 24, lines 28-31. A reflective surface inherently reflects light if the light is not attenuated or absorbed by a substance, including a cell on the disc. Therefore, although the reference does not explicitly teach the limitation where "light directed to the capture zone and not striking a cell is reflected", one of ordinary skill in the art would recognize that a reflective surface would reflect light that is not attenuated or absorbed.

In regards to claim 4, Sheppard, Jr. et al teach that platforms can comprise an optically transparent surface that permits a direct light path through the surface of the platform (i.e. light directed to the capture zone is transmitted through the optical disc), wherein the light source and detector are positioned on opposite sides of the platform (i.e. disc being between the light source and a detector). See column 24, lines 20-26. A transparent surface inherently transmits light through the surface if the light is not attenuated or absorbed by a substance, including a cell. Therefore, although the reference does not teach the method where light directed to the capture zone and not striking a cell is transmitted, one of ordinary skill in the art would recognize that a transparent surface would transmit light that is not attenuated or absorbed.

In regards to claim 5, Sheppard, Jr. et al teach that specific binding reagents comprising a first member of a specific binding pair is provided coating a surface or detection chamber of a platform (i.e. coated with a first group of cell capture reagents). See column 10, lines 46-48.

In regards to claim 6, Sheppard, Jr. et al teach that the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or detection chamber are treated with a specific binding reagent and others are not in a recognizable manner (i.e. cell capture agents define a capture zone). See column 10, lines 60-63.

In regards to claim 7, Sheppard, Jr. et al teach that each of a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber of a platform, thereby providing a pattern of such distinct

specific binding reagents on the platform (i.e. a second group of cell capture agents define a second capture). See column 11, lines 5-9.

In regards to claim 8, Sheppard, Jr. et al teach that the first and second capture zones are in one chamber, by disclosing a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber (i.e. first and second capture zones are in one chamber). See column 11, lines 5-7.

In regards to claim 9, Sheppard, Jr. et al teach that specific binding reagents coated to a surface or detection chamber of a platform is intended to detect a cell expressing a cognate antigen (i.e. cell surface antigen). See column 10, lines 45-50.

In regards to claims 10-11, Sizto et al teach CD4 and CD8 antigens, as stated above. See column 6, lines 17-33.

In regards to claim 12, Sheppard, Jr. et al teach that the sample is driven into a binding/detection chamber (and contacts the surface coated with the specific binding reagent (i.e. directing the sample of cells into proximity with the cell capture agents), wherein the sample is incubated in the chamber (i.e. incubating the cells), and wherein the cells are bound to the chamber (allowing cells to bind to capture agents). See column 34, lines 29-45.

In regards to claim 13, Sheppard, Jr. et al teach the step of disclosing visually observing the number of cells bound to the chamber (i.e. analyzing the number of cells). See column 34, lines 44-45.

In regards to claims 14 and 30, Sheppard, Jr. et al teach that particles adsorbed to the surface of the waveguide will both scatter and absorb light, and that the amount of radiation transmitted to the detector that is depressed relative to clean waveguides can be used to infer the number of adsorbed particles (i.e. detecting sufficiently large changes in a level of light transmitted through the disc). See column 23, lines 15-20 and column 24, lines 50-54.

In regards to claims 15, 21 and 31, Sheppard, Jr. et al teach that visual inspection of the reaction chamber can be used to resolve cells by a computer-aided vision system (i.e. image recognition) and that preferred embodiments include detecting and quantitating individual particles, preferably cells (i.e. count captured cells in each of the capture zones). See column 32, lines 30-35 and 40-43.

In regards to claim 17, Sheppard, Jr. et al teach that arrays can be discrete arrays each comprising a different specific binding reagent (i.e. each capture zone having a different cell capture agent). See column 11, lines 9-12.

In regards to claim 18, Sheppard, Jr. et al teach that the rotation speed of the invention is increased to drive a milk sample into the binding/detection chamber, where it contacts the surface coated with the specific binding reagent and the sample is incubated in the chamber for 30 minutes (i.e. rotating for a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with capture molecules). See column 34, lines 29-32. In addition, since Sheppard et al teach that following incubation, the rotation rate is "increased", which inherently implies that there was rotation during the incubation period and therefore, the rotation period during the 30

minutes incubation was to apply a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with the capture molecules.

In regards to claims 19-20, Sheppard, Jr. et al reference teaches that the step of increasing the rotation rate after incubation so that a wash buffer flushes the milk sample out of the chamber and into the waste receptacle (i.e. rotating for a sufficient period of time at a single speed sufficient so that unbound cells are moved away from the capture zones). See column 34, lines 32-37. In addition, the reference also teaches that after removal of the milk sample, a binding assay is performed on cells bound to the disc. See column 34, lines 37-47. Although Sheppard, Jr. et al reference does not explicitly teach the limitation of "rotating for a sufficient period of time", a certain time period of rotation is necessarily required in order to completely remove unwanted materials, including unbound cells, from the capture zone since instantaneous removal is not technically possible. In addition, a minimal rate of rotation is necessarily required in order to effectively remove liquid samples from a chamber in a disc, including unbound cells from the capture zones. Since Sheppard, Jr. et al reference teaches a binding assay performed after removal of milk sample through rotation, a "sufficient speed" is necessarily required to have been applied to remove unbound cells in order to perform the binding assays on immobilized cells.

In regards to claim 22, Sizto et al reference teaches obtaining CD4/CD8 T-cell ratios (i.e. ratio of CD4 to CD8 cells), as stated above. See column 6, lines 17-33.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238), as applied to claims 1 and 12-15 above, and further in view of Miller et al (USP 4,307,367).

Sheppard et al and Sizto et al references have been disclosed above, but fail to teach the method of using image recognition to distinguish one type of white blood cell from another.

Miller et al teach that pattern recognition can be used to determine a white blood cell differential count, which detects cell types, in order to determine the health of a person whose blood sample is being examined. See column 1, lines 25-29.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard, Jr. et al and Sizto et al, the method of using image recognition to determine a white blood cell differential count which detects cell types, as taught by Miller et al, in order to determine the health of a person whose blood sample is being examined. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using image recognition to determine a while blood cell differential count, as taught by Miller et al, in the method of Sheppard, Jr. et al and Sizto et al, since Sheppard, Jr. et al and Sizto et al teach that computers with image processing and a computer-aided vision system can be used to resolve cells, and the pattern recognition taught by Miller et al is one example of image processing.

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238) as applied to claim 1 above, and further in view of Van der Merwe et al (US 4,478,946) and Oflenloch-Hahnle et al (US 5,212,063).

Sheppard, Jr. et al and Sizto et al references have been disclosed above. In addition, Sheppard, Jr. et al reference additionally teaches that the specific binding reagent on the disc surface is an antibody (i.e. first antibody). See column 16, lines 18-20. Furthermore, Sizto et al reference teaches antibodies to CD4 (i.e. cell surface antigen). See column 6, line 3. However, the references fail to teach a first layer of streptavidin, that the first antibody is raised in a first species against a type of immunoglobulin of a second species, and that a second antibody is raised in the second species.

Van der Merwe et al reference teaches a double layer with sheep IgG antibodies in a first layer raised against rabbit IgG, and a second layer of rabbit IgG specific against an antigen, in order to provide a means for orienting the second layer outward from the substrate. See column 5, lines 17-19 and column 10, lines 40-52.

Oflenloch-Hahnle et al reference teaches a surface coated with streptavidin, in order to immobilize an antibody to a solid phase, wherein the antibody is biotin-labeled. See column 8, lines 25-48.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sheppard, Jr. et al and Sizto et al with a double layer with sheep IgG antibodies in a first layer raised against rabbit IgG, and a second layer

of rabbit IgG specific against an antigen, as taught by Van der Merwe et al, in order to provide a means for orienting the second layer outward from the substrate, and with a surface coated with streptavidin, as taught by Oflenloch-Hahnle et al, in order to immobilize an antibody to a solid phase, wherein the antibody is biotin-labeled. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a double layer of antibodies, as taught by Van der Merwe et al and including a streptavidin-coated surface, as taught by Oflenloch-Hahnle et al, in the method of Sheppard, Jr. et al and Sizto et al, since Sheppard, Jr. et al and Sizto et al teach solid phase immunoassays, and the antibody double-layer and streptavidin-coated surfaces are also applied to solid phase immunoassays.

13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238) as applied to claim 1 above, and further in view of Mian et al (US 6,319,469 B1) and Christian (US 4,673,657).

Sheppard, Jr. et al and Sizto et al references have been disclosed above, but fail to teach a control and that the capture zones are located in a fluid path between the inlet port and the vent port.

Mian et al reference teaches air outlet ports 29 and 33-35, wherein outlet 29 is farther down the fluid flow from the center inlet and reaction chambers 16, 22, and 24, in order to provide a means for fluids to displace air and ensure uninhibited movement of fluids on the disk. See column 3, lines 36-57; column 4, lines 47-52; and Figures 1A-C.

Christian reference teaches positive and negative controls, in order to aid in quantitation and detect false negatives or positives. See column 13, lines 41-49.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sheppard, Jr. et al and Sizto et al with air outlet ports 29 and 33-35, wherein outlet 29 is farther down the fluid flow from the center inlet and reaction chambers 16, 22, and 24, as taught by Mian et al, in order to provide a means for fluids to displace air and ensure uninhibited movement of fluids on the disk, and with positive and negative controls, as taught by Christian, in order to aid in quantitation and detect false negatives or positives. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including air outlet ports down the fluid flow from a center inlet and reaction chambers, as taught by Mian et al, and including positive and negative controls, as taught by Christian et al, in the method of Sheppard, Jr. et al and Sizto et al, since Sheppard, Jr. et al and Sizto et al also teach air vents and serial placement of different capture zones.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-22 and 30-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of copending Application No. 10/230,959 in view of Sheppard, Jr. et al (USP 6,143,247) and Sizto et al (USP 5, 962, 238).

Claims 1-22 and 30-33 of the instant application disclose a method of conducting an assay, the method comprising providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent, the disc including at least one inlet port and a vent port on a first surface of the disc, loading the disc into an optical reader, rotating the disc so as to separate different cell types into different capture zones, directing an incident beam of electromagnetic radiation to the capture zone, detecting a beam of electromagnetic radiation formed after interacting with the disc as the capture zone, converting the detected beam into an output signal, and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone, counting captured cells in each of the capture zones, and providing an output including the counts, wherein the output includes counts for CD4 cells and CD8 cells.

Claims 2-11 of the copending application disclose all of the limitations of the instant application with the exception of the disc including at least one inlet port and a vent port on a first surface of the disc, rotating the disc so as to separate different cell

types into different capture zones, counting captured cells in each of the capture zones, and providing an output including the counts, wherein the output includes counts for CD4 cells and CD8 cells.

Sheppard, Jr. et al reference teaches a platform with sample input means, air displacement vents, detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number of cells on the platform can be processed, in order to identify particular cells or cell types in a biological sample. See column 3, lines 29-38; column 11, lines 1-25; column 21, lines 57-67; column 26, lines 55-56; and Example 1.

Although Sheppard, Jr. et al reference does not explicitly teach rotating the disc so as to separate different cell types into different capture zones, the instant reference teaches the instant limitation by disclosing disc rotation and a series of binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since the reference teaches rotation of the disc, centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Cell types in a fluid sample would be captured by the distinct specific binding reagents in different regions of the disc, either in the detection chambers or in different regions of the "bar code" or

concentric circles within a detection chamber, thereby separating cell types into different capture zones.

Sizto et al reference discloses determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD8 T-cell ratios, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS. See column 6, lines 17-33.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the copending application with a platform with sample input means, air displacement vents, detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number of cells on the platform can be processed, as taught by Sheppard, Jr. et al, in order to identify particular cells or cell types in a biological sample, and to modify the method of the copending application with the step of determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD8 T-cell ratios, as taught by Sizto et al, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in rotating the disc to separate cells, as taught by Sheppard, Jr. et al, and to count CD4 and CD8 cells, as taught by Sizto et al, in the method of the copending application since both the copending application and Sheppard, Jr. et al teach a rotating optical disk for detecting

and counting cells, and CD4 and CD8 cells taught by Sizto et al are examples of cells that can be detected.

This is a provisional obviousness-type double patenting rejection. This rejection also applies to claims 1-10 and 13-46 of copending Application No. 10/233,322 and claims 17-23 of copending Application No. 10/293,214.

Response to Arguments

16. Applicant's arguments filed 25 March 2005 have been fully considered but they are not persuasive. On pages 7-8 of the Remarks, Applicant indicates that Sheppard, Jr. et al reference fails to teach of suggest the usage of a vent port. However, as indicated in the rejection under 35 U.S.C. 103(a) supra, the reference does teach a vent by disclosing air displacement vents. See column 3, lines 36-37.

17. Applicant's arguments with respect to claims 32 and 33 have been considered but are moot in view of the new ground(s) of rejection.

18. On page 8, it is noted that Applicant has failed to address the non-provisional double patenting rejections set forth in the previous Office Action and states that the rejections will be addressed once the provisional double patenting rejections become non-provisional. Applicant is directed to M.P.E.P. § 804, which states:

B. Between Copending Applications—Provisional Rejections

Occasionally, the examiner becomes aware of two copending applications filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. In re Mott, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); In re Wetterau, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

Therefore, since provisional double patenting rejections are proper, the rejection is maintained and has been restated supra.

In addition, on page 8, Applicant states the provision double patenting rejections are improper because the references applied are not owned by assignee, and cites section 804 of the M.P.E.P. Applicant is directed to the first paragraph of the double patenting rejection, which clearly indicates that the primary reference is ***copending Application No. 10/230,959*** and has the same assignee as the instant application. Secondary references Sheppard, Jr. et al and Sizto et al are not required to have the same assignee as the instant application. Therefore, since the primary reference is co-assigned with the instant application, Applicant's argument is not persuasive.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641

LYL

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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